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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/774,092	BROVELLI ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/09/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,6,7 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,6,7 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 3, 6-7 and 23-25 are pending in the application and were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 6-7 and 23-25 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended claims 3 and 24 to recite:

"(i) a standardized concentration of the marker compound that is used to prepare an extract…". This phrase is considered New matter because there is nowhere in the specification which teaches that the maturation stage *is selected* with a standardized concentration of the marker compound. The Instant specification teaches that chicoric

acid levels were measured from plants in various maturation stages, however, that the levels of chicoric acid were relatively similar. The natural content of the chicoric acid is not considered 'standardization'; rather, standardization is what occurs after the extract is collected; it is a means for manipulating the extract to contain certain levels of a compound. Further, Applicant has not pointed out in the specification that the concentrations of chicoric acid would be considered to be 'standardized.'

In order to overcome this rejection; Applicant is asked to either delete the New Matter in the claim, or to point out specifically where this information can be found.

Because claims 4-7, 23 and 25 depend upon either claims 3 or 24 respectively, claims 6-7, 23 and 25 necessarily contain all of the limitations of either claims 3 or 24 respectively and therefore also contain New Matter and are appropriately rejected under this statute.

Applicants' arguments were fully considered, but not found persuasive.

Applicants' initially argue that 'one would know the metes and bounds of a standardized concentration of marker compound: "Standardization of extract has a well-understood meaning. A standardized concentration of a marker compound merely means that each extract having a standardized concentration of a marker compound

has the same concentration of that marker compound….the important aspect is that the level of marker compound remains consistent…" (p. 6, Remarks).

However, it is reminded that this rejection is set forth under 35 USC 112 First paragraph, and not 35 USC 112 Second paragraph. Applicants appear to be traversing an apparent rejection under 112 Second paragraph for lacking indefiniteness; however, no such rejection was made of record.

Applicants argue that Table 1 and paragraphs 0022 offer support for "(i) a standardized concentration of the marker compound that is used to prepare an extract…" in that these portions of the specification "report that levels of chicoric acid do not vary greatly from plant to plant at maturation stages 1 to 6." (p. 6, Remarks). Hence, Applicants surmise that "one of ordinary skill in the art would appreciate that a standardized concentration of the marker compound chicoric acid would fall in the range of 3.49 ± 0.09% to 3.54 ± 0.14%.'

However, the amounts of chicoric acid as found in the plant material are not 'standardized' meaning, they have not been altered from their original content as found endogenously within the plant material. Applicants argue that 'standardized' refers to a useful industry measurement wherein suppliers insure that each extract has the same level of a marker compound. . However, Applicants have not disclosed any level of chicoric acid which they deem to be standardized. Claim 3 states '…selecting a

maturation stage with (i) a standardized concentration of the marker compound that is used to prepare an extract of the Echinacea plant…'. The amounts of chicoric acid, as agreed to by Applicants, vary from plant to plant. What is the 'standardized concentration' which the claim is refering to? This is not known because there is nowhere in the Instant specification as filed which indicates that Applicants chose a level of chicoric acid which they deemed to be 'standardized.' To reiterate from the previous Office action, "The natural content of the chicoric acid is not considered 'standardization;' rather, standardization is what occurs after the extract is collected [prepared]; it is a means for manipulating the extract to contain certain levels of an analyte compound.

Judging from the specification as a whole, Applicants did not standardize levels of chicoric acid. While Applicants measured the amount of chicoric acid at each maturation stage, the choice of plant was not based upon the amount of chicoric acid, but based upon the 'highest level of immune-stimulatory product' (see claim 3, part (ii)). The amount of chicoric acid in the extracts was not standardized and was similar from batch to batch as taught in the Specification. However, now, Applicants are claiming that they have standardized a concentration of chicoric acid or chlorogenic acid which is New Matter because Applicants did not contemplate this method step at the time the invention was made. On the contrary, it appears that Applicants were aware of the amount of chicoric acid in the plants in the various maturation stages, however, the plants were not chosen based upon the amount of chicoric acid, and no manipulation

(i.e., standardization) of chicoric acid or chlorogenic acid occurs in the disclosure as originally filed.

Further, the immunopotentiating studies of the individual extracts (see p. 8, Specification) was carried out after a water/dimethyl sulfoxide/ethanol extraction. It is not known what concentration of chicoric acid or chlorogenic acid was present in the extracts which were used for immunopotentiating determination as carried out on pp. 6-9 for example because Applicants did not disclose this information. The extracts as tested by Applicants could potentially be devoid of either claimed marker. Hence, this is additional evidence that Applicants did not standardize either marker of chicoric acid or chlorogenic acid for preparing an extract in that these marker compounds were not quantified after the extract was prepared. The plants were not chosen based upon marker compounds, the plants were all harvested (or a portion of plants from each maturation stage) and tested for immunopotentiating activity and chosen strictly based upon this activity. Again, it is not even known if the claimed marker compounds were present in the extract prepared by Applicants.

Gahler et al. reported that:

> (8) Thus, there is a need for methods for efficiently extracting polysaccharides, alkylamides and chicoric acid from Echinacea plants, and for Echinacea extracts containing a high concentration of polysaccharides, alkylamides and/or chicoric acid. **Further, there is a need for standardized Echinacea compositions containing a predetermined, desired amount of Echinacea extracts, including polysaccharide, alkylamide and/or chicoric acid extracts.**

Thus, Gahler et al. support the Examiner's contentions; a standardized preparation is one in which a 'predetermined, desired amount' of an analyte component is incorporated *into an extract*. Applicants have not provided a 'predetermined, desired amount' of chicoric acid in an extract. The only quantification of chicoric acid was done by Applicants in the plant material itself, and to reiterate from above, Applicants did not even determine if either of chicoric acid or chlorogenic acid were present in the extract which was used for testing (again, see p. 6, Specification). Thus, Applicants did not appear to contemplate 'a standardized concentration of the marker compound that is used to prepare an extract of the Echinacea plant' which is broad enough to be interpreted to mean that *the extract contains a standardized amount of the marker compound.*

Although it is deemed that 'a standardized concentration of the marker compound that is used to prepare an extract of the Echinacea plant' is new matter, the claims are still examined with regard to their scope, including the additional new matter.

Claim Rejections - 35 USC § 103

Claims 3, 6-7 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over A in view of C in view of E or B in view of C in view of E; wherein A = Seidler – Lozykowska et al. (2003), B= Dou et al. (2001 – Abstract), C= Rininger et al. (2000) and E= Gahler et al. (US 6,511,683) for the reasons keenly made of record. Seidler – Lozykowska et al. may be referred to as "SL et al."

Claims 3, 6-7 and 23-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over A in view of C in view of D in view of E or B in view of C in view of D in view of E; wherein A = Seidler – Lozykowska et al. (2003), B= Dou et al. (2001 – Abstract), C= Rininger et al. (2000) D= Wyllie et al. (US 2003/0235890) and E= Gahler et al. (US 6,511,683) for the reasons keenly made of record. Seidler – Lozykowska et al. may be referred to as SL et al.

Applicants' arguments were fully considered, but were not found persuasive.

Applicants have amended the claims to require that the marker compounds are specifically chlorogenic acid or chicoric acid. The prior Office action clearly took into account the claims as if they were directed toward chlorogenic acid or chicoric acid and therefore, this limitation has already been addressed on the record and found obvious based upon the combined teachings of the prior art.

Response to Arguments

Applicants' arguments were fully considered, but not found persuasive.

Applicants argue:

> …according to Section 2141 of the MPEP, when applying 35 U.S.C. 103, the following tenants of patent law must be adhered to: (A) The claimed invention must be considered as a whole; (B) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) the references must be viewed without the benefit of impermissible hindsight…; and (D) reasonable expectation of success is the standard with which obviousness is determined. Hodosh v. Block Drug Co., Inc…Applicants thus comment that "Under these standards, the claims are not obvious in view of the cited references. First the claimed invention as a whole is a method for determining optimal harvest window of Echinacea, based on selecting a plant maturation stage that has both a concentration of a marker compound that is greater than zero and acceptable for preparing a standardized extract, and immonostimulatory activity. the claimed method also includes a step of preparing a standardized extract at that selected maturation stage. (p. 8, Remarks).

It is noted that the Examiner has based her rejections upon the 'Graham inquiries; that is:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Based upon these factors, it is determined that the claimed invention as a whole is obvious in view of the combination of the cited prior art references for reasons keenly pointed out in previous Office actions, as well as herein.

It is noted that the prior art does not specifically teach all of the claim limitations in one reference, hence, there is no 102 rejection. However, the invention as a whole is rendered obvious by the prior art references. Echinacea plants were well-known in the art at the time the invention was made and exhaustively studied for their medicinal effects. The claimed invention as a whole is obvious, and there is no individual step in any of the method claims which was not already known or made obvious by the prior art. That is, there is no novel step or idea in the method claims which makes it unobvious over the prior art references. According to the prior art references, as keenly pointed out in the previous Office action, Echinacea plants were known to be studied at different maturation stages for marker compounds to select for optimum levels of compounds. Echinacea plants were also known to contain immunopotentiating activity, and the activities were known to be studied and already determined to depend, in part, upon the harvesting time of the Echinacea. Additionally, Applicants' method for determining the level of immunopotentiating activity, as well as marker immuno stimulatory products were known in the art at the time the invention was made. While no one, individual reference taught all of these steps together; the ordinary artisan would have been motivated to perform the claimed method in order to optimize medicinal efficacy of an Echinacea extract and standardization would have been routine

in manufacturing extracts with essentially uniform chemical constituents and hence, medicinal effectiveness: ***"[a] person of ordinary skill is also a person of ordinary creativity, not an automaton*** *KSR* 127S. Ct. at 1742 (emphasis added).

Applicants argue that the cited references do not teach the method of the claimed invention: "…in fact they teach away from using the two specific marker compounds chicoric acid or chlorogenic acid. Two of the cited references, Seidler-Lozykowska and Dou, examine when the greatest levels of typical marker compounds used to standardize extracts may be obtained and from which specific parts of the plants they may be obtained. Neither Sieidler-Lozykowska nor Dou discuss any immunopotentiating activity of Echinacea....Rininger and Gahler teach that standardized extracts using chlorogenic acid or chicoric acid as marker compounds do not exhibit immunostimulatory activity" (p. 9, Remarks).

However, Applicants have not provided substantiating evidence to verify that the prior art in fact 'teaches away' from the claimed invention. The concept of the claimed invention is very broad, even broader than the scope of the nature of the invention as described in the original specification (see New matter rejection, *supra*). Claim 3 for example is directed toward harvesting Echinacea at a plurality (more than one) maturation stage, producing a preparation for each maturation stage, assaying immune-stimulatory products induced by each preparation, determining the concentration of chlorogenic acid or chicoric acid in each preparation and selecting a

maturation stage with a standardized concentration of the marker compound (chlorogenic acid or chicoric acid) and 'the highest level of immune-stimulatory product.' Here, a 'standardized concentration' can be *any* concentration of chicoric acid because the claim does not state any particular concentration. Maturation stages of Echinacea were clearly recognized to produce varying levels of immunopotentiating activity as reported by Gahler et al. :

> Numerous factors must be considered and optimized in order to produce Echinacea extracts having a high concentration of polysaccharides, alkylamides and/or chicoric acid. For example, the amounts of polysaccharides, alkylamides and chicoric acid in Echinacea plants are influenced by the species of the plant, the age of the plant and the plant growth conditions. Additionally, the solvents and process parameters, such as temperature and length of extraction period, utilized to extract polysaccharides, alkylamides and chicoric acid from Echinacea plants can greatly affect the yield of these components.
>
> (8) Thus, there is a need for methods for efficiently extracting polysaccharides, alkylamides and chicoric acid from Echinacea plants, and for Echinacea extracts containing a high concentration of polysaccharides, alkylamides and/or chicoric acid. Further, there is a need for standardized Echinacea compositions containing a predetermined, desired amount of Echinacea extracts, including polysaccharide, alkylamide and/or chicoric acid extracts.

Thus, the claim is broad enough to read on harvesting Echinacea plants (known in the art), assaying the maturation stages for immunopotentiating activity (known in the art) and selecting a maturation stage with a 'standardized concentration' (= any concentration of chlorogenic acid or chicoric acid') and the highest level of immune-stimulatory product and preparing a standardized extract of the Echinacea plant. Here, the last part of claim 3 'and preparing a standardized extract of the Echinacea plant' does not state that the extract is standardized for chlorogenic acid or chicoric acid;

rather, it broadly states 'standardized extract' which may be directed toward standardization of any analyte compound; in other words, the resulting extract does not necessarily contain any marker compound.

Again, it is noted that Applicants point to one embodiment of Rininger which discusses a single standardized extract containing 4% phenolic standardized extract did not induce macrophage stimulation. This does not indicate that all extracts from Echinacea standardized for chicoric acid will be inactive for immunopotentiating activity. This is clearly an improper characterization of Rininger, especially considering that Gahler et al. clearly teaches that extracts of Echinacea standardized for chicoric acid have immunopotentiating activity (see, e.g., Fig. 1). Additionally, there is no indication in the claims that the extract prepared has *any amount of a marker compound*.

Applicant argues that Gahler teaches that chicoric extracts of Echinacea 'had no significant effect on the phagocytic activity or the phagocytic index of rat alveolar macrophages' (Col. 24, lines 29-38), that the Echinacea polysaccharide extract…had no significant effect on the phagocytic activity and that 'Echinacea chicoric acid and polysaccharide extracts…did not significantly increase the level of nitric oxide production by alveolar macrophages' (col. 24, lines 64-67). (p. 10, Remarks).

However, it is noted that while these extracts did not perform significantly, each respective extract did cause an increase in phagocytic activity (see Figure 1 and col. 24, lines 22-29). There is no level of 'immune stimulation' provided by the claims, only that 'the highest level' of immune stimulation; as determined by assaying the plant material, is chosen for extraction based upon a minimum of 2 maturation stages of plant samples. Further, the amount of chicoric acid or chlorogenic acid appears to be immaterial to the claimed invention; rather, the only requirement is that an amount of either of these components is measured in the plant material. Apparently, there is chicoric acid in all Echinacea plants at any harvest time. Thus, the claims are broad enough to read on wherein the Echinacea plants are harvested at the various maturation stages, tested for immunopotentiating activity, and choosing the plant stage based solely on the immunopotentiating activity, wherein the marker compound is simply identified ('determining a concentration').

Applicants argue that ""…some Echinacea extracts standardized by multiple marker compounds can be harvested at certain maturation stages to optimize immunostimulatory activity…Echinacea extracts standardized with only one marker compound, particularly only chicoric acid will show ***no immunostimulatory activity***' (p. 10, Remarks, emphasis in Applicants' original Remarks). However, this argument is without merit because Gahler et al. clearly shows that the chicoric acid extract did increase phagocytic activity, clearly indicating immunopotentiating activity of the chicoric acid extract (see, Id.) even if it was not superior to the extract containing all three

markers. "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments." *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) In the Instant case, the choice of plant material which showed the highest immunopotentiating activity would have been *an obvious choice to one of ordinary skill in the art* familiar with Echinacea medicinal activity and phytochemicals. Further, the extract produced by the method of the Instantly claimed invention is not standardized for *any particular amount of marker compound* and there is nowhere in the claim which particularly states that the extract prepared from the plant preparation even contains *any amount* of the marker compound. It is respectfully believed that Applicants are interpreting their claims in a more narrow light than the broad breadth in which they are actually presented.

Additionally, it is pointed out that Applicants are arguing limitations which are not found in the claim. The claim *does not exclude* the choice of other marker compounds such as polysaccharides. Applicants' method uses 'comprising' language which allows for the incorporation of unspecified, unclaimed, undisclosed method steps.

Applicants summarize their arguments by stating that the prior art did not

> Applicants respectfully submit that when the claims are considered in their entirety and when the references also are considered as a whole, without relying on impermissible hindsight, it is clear that the cited references do not provide any reasonable expectation of success in formulating a method for determining optimal harvest window of Echinacea, based on selecting a plant maturation stage that has both a standardized concentration of either chicoric acid or chlorogenic acid as a marker compound that is obtained from the preparation of Echinacea plant for preparing a standardized extract, and that has immunostimulatory activity. Specifically, Seidler-Lozykowska and Dou both teach means for producing Echinacea extracts with the highest concentration of compounds used to standardize Echinacea extracts. Rininger teaches that neither standardized Echinacea extracts nor the common marker compounds used for standardization particularly chlorogenic acid and chicoric acid exhibit immunostimulatory activity. Gahler teaches that standardized extracts using multiple marker compounds in combination can produce immunostimulatory activity, but Gahler specifically teaches away from using only one marker compound to standardize the extracts, and particularly teaches that Echinacea extracts standardized using chicoric acid do not have immunostimulatory activity. Thus, one of skill in the art would not, based on the teaches of the cited references, expect the claimed method of optimizing harvest window of the Echinacea plant by selecting a plant maturation stage that has a standardized concentration of either chicoric acid or chlorogenic acid, yet also maintains immunostimulatory activity, to be successful.

However, the Examiner is not persuaded by Applicants' arguments. Applicants' method merely indicates that a plant maturation stage is chosen based upon any amount of chlorogenic or chicoric acid, and wherein the preparation displays the highest level of immune-stimulatory activity. Merely based upon Gahler et al. alone, one of ordinary skill in the art would have a reasonable basis for success seeing that Gahler et al. clearly showed that chicoric acid extracts of Echinacea displayed immunopotentiating activity. Based upon this fact, and based upon the fact that Gahler clearly taught that levels of analyte compounds varied dependent upon the species, age and plant growth conditions, the ordinary artisan would have been motivated to plant Echinacea and determine the optimum time for harvesting based upon the amount of chicoric acid for example, and to further test for immunopotentiating activity

and to chose a plant for extraction based upon known, conventional knowledge and assays.

It remains deemed that the claimed invention is an obvious variation of known, conventional knowledge and techniques found in the prior art. There is no inventive concept in the claims which rises to the level of patentability in that there is no one claim limitation which is non-obvious from the prior art. Applicants' claims, directed toward choosing a plant with a 'standardized' amount of chicoric acid for example, are broad enough to read on *any amount of chicoric acid*. Chicoric acid was a well-known, desired compound derived from Echinacea. Harvesting Echinacea plants based upon the level of Chicoric acid would therefore have been obvious. Having the knowledge that the amount of immunopotentiating compounds vary based upon the age of the plant, assaying each respective maturation stage for optimum immunopotentiating activity would have been *prima facie* obvious at the time the invention was made considering the teachings of the prior art. Measuring the content of chicoric acid in an Echinacea plant preparation which exhibited 'the highest' level of immunopotentiating activity would have been obvious based upon the fact that chicoric acid is a known, immunopotentiating agent: "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton *KSR* 127S. Ct. at 1742.

The Supreme court has acknowledged that:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable varition..103 likely bars its**

> **patentability**…if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions…

…**the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results** (see *KSR International Co. v. Teleflex Inc*., 82 USPQ2d 1385 U.S. 2007) emphasis added.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

/Patricia Leith/

Primary Examiner, Art Unit 1655